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Washington, D.C. 20231 SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/270,152 07/01/94 BOUSSIOTIS EXAMINER HUTZELL, P 18M2/1004 ART UNIT PAPER NUMBER AMY E MANDRAGOURAS LAHIVE AND COCKFIELD 60 STATE STREET BOSTON MA 02109 1806 DATE MAILED: 10/04/95 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Responsive to communication filed on This action is made final. month(s), 3A shortened statutory period for response to this action is set to expire _ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: Notice of References Cited by Examiner, PTO-892. 2. Notice of Draftsman's Patent Drawing Review, PTO-948. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474... Part II SUMMARY OF ACTION are pending in the application. Of the above, claims are withdrawn from consideration. 2. Claims_ are allowed. 4. Claims are rejected. 5. Claims 6. \(\sum \) Claims \(\sum \) are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on _ . Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on _ __. has (have) been approved by the examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed _ _, has been approved; disapproved (see explanation). 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received Deen filed in parent application, serial no. _ _____; filed on _ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

- 15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1-10, drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an agent that binds to the cytokine receptor gamma chain, classified, for example, in Class 424, subclasses 144.1 and 85.2.
- II. Claims 11-18, drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an agent that acts intracellularly to stimulate phosphorylation of JAK kinase, classified, for example, in Class 514, subclass 44
- III. Claims 19-44, drawn to methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma chain, classified, for example, in Class 424, subclass 144.1 and 145.1.
- IV. Claims 45-47, drawn to methods for identifying an agent inhibits delivery of a signal through a cytokine receptor gamma chain, classified, for example, in Class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-IV differ in the method objectives, method steps and parameters and in the reagents used. Group I contains claims drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an

agent that binds to the cytokine receptor gamma chain. Group II contains claims drawn to methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an agent that acts intracellularly to stimulate phosphorylation of JAK kinase. Group III contains drawn to methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma chain. Group IV contains claims drawn to methods for identifying an agent inhibits delivery of a signal through a cytokine receptor gamma chain. These methods are clearly distinct.

16. Upon the election of Group I, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: I) Methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using IL-4; II) Methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using IL-7; III) Methods for stimulating proliferation by a T cell which expresses a cytokine receptor gamma chain using an anti-gamma chain antibody.

The methods of species I-III differ in the method objectives, method steps and parameters and in the immunological reagents used. The examination of species I-III would require different searches in the U.S. Patent shoes and in the scientific literature and would involve the consideration of separate issues in determining

patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 4-10 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

17. Upon the election of Group III a further election of species is required as follows:

This application contains claims directed to the following patentably distinct species of the claimed invention: I) methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma chain using an agent that acts extracellularly to inhibit delivery of a signal through a cytokine gamma chain; II) methods for inducing unresponsiveness to an antigen in a T cells which expresses a cytokine receptor gamma

chain using an agent that acts intracellularly to inhibit delivery of a signal through a cytokine gamma chain.

The methods of species I and II differ in the method steps and parameters and in the reagents used.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19 and 37 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Upon the election of species I above, a further election of species is required: among methods using an agent which is i) an anti-gamma chain antibody ii) an anti-IL-7 antibody; iii) an anti-IL-4 antibody and iv) an anti-IL-2 antibody. The methods of species i-iv in the method parameters and in the immunological reagents used. The examination of species i-iv would require

different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Upon the election of species II, above, a further election of species is required among: methods of using an agent which acts intracellularly to inhibit delivery of a signal through the cytokine receptor gamma chain selected from i) an agent which inhibits association of the cytokine receptor gamma chain with a JAK kinase; ii) an agent that inhibits tyrosine phosphorylation of a JAK kinase; iii) an agent which inhibits tyrosine phosphorylation of the cytokine receptor gamma chain.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paula Hutzell, Ph.D, whose telephone number is (703) 308-4310. The Examiner can normally be reached on Monday-Thursday from 9:00 AM-6:00 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Margaret Parr, can be reached on (703)-308-2454. The fax phone number for this Group is (703)-305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PAULA K. HUTZELL PRIMARY EXAMINEP GROUP 1800